

PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, December 19, 2000, 10:00 a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Dr. Howard Koh (Chairman), Dr. Clifford Askinazi, Ms. Phyllis Cudmore, Mr. Manthala George, Jr., Mr. Albert Sherman (arrived at approximately at 10:10 a.m.), Ms. Janet Slemenda; and Ms. Shane Kearney Masaschi, Mr. Benjamin Rubin and Dr. Thomas Sterne were absent. Also in attendance was Attorney Donna Levin, General Counsel.

Chairman Koh announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A 1/2.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Ms. Nancy Ridley, Assistant Commissioner, Bureau of Health Quality Management, Dr. Paul Dreyer, Director, Division of Health Care Quality; Ms. Joyce James, Director, and Ms. Holly Phelps, Consulting Analyst, Determination of Need Program; and Attorney Carl Rosenfield, Deputy General Counsel, Office of the General Counsel.

PERSONNEL ACTIONS:

In letters dated December 7, 2000, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of the appointments and reappointments to the provisional consultant, provisional affiliate and provisional active medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously)[Council Member Sherman not present to vote]: That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning December 1, 2000 to December 1, 2002:

<u>APPOINTMENTS</u>	<u>STATUS/SPECIALTY</u>	<u>MEDICAL LICENSE NO.</u>
---------------------	-------------------------	----------------------------

John Santopietro, M.D.	Provisional Active Psychiatry	156555
David Sidebottom, M.D.	Provisional Consultant Infectious Disease	48047
Julieta Austria, M.D.	Provisional Affiliate/Internal Medicine	51406
Thomas Roberts, M.D.	Provisional Affiliate /Internal Medicine	205670

<u>REAPPOINTMENTS</u>	<u>STATUS/SPECIALTY</u>	<u>MEDICAL LICENSE NO.</u>
-----------------------	-------------------------	----------------------------

Katherine Domoto, M.D.	Active	39561
David Gendelman, M.D.	Consultant	55101
Richard Oman, EdD	Allied	2545
Alan Siegel, EdD	Allied	101

In a letter dated December 11, 2000, Karen Vicario, Acting Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of an appointment and reappointments to the medical and allied staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously)[Council Member Sherman not present to vote]: That, in accordance with the recommendation of the Acting Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointment and reappointments to the medical and allied medical staffs of Lemuel Shattuck Hospital be approved as follows:

<u>PHYSICIAN REAPPOINTMENTS</u>	<u>STATUS/SPECIALTY</u>	<u>MEDICAL LICENSE NO.</u>
-------------------------------------	-------------------------	----------------------------

Salvatore Mangano, M.D.	Consultant/Surgery	22042
Daniel Naiman, M.D.	Active/Psychiatry	45442
Elliot Pitrel, M.D.	Active/Psychiatry	53914

LEMUEL SHATTUCK**HOSPITAL CONTINUED:****ALLIED HEALTH
PROFESSIONAL –
APPOINTMENT****SPECIALTY****MEDICAL LICENSE NO.**

Elizabeth Mastroianni, N.P.

Internal Medicine

229246

**CATEGORY 2 APPLICATION: PROJECT APPLICATION NO. 5-4885 OF FOUR
WOMEN, INC.:**

For the record, this item was taken out of turn, after docket item No. 2 Personnel Actions and Council Member Sherman arrived during Ms. Phelps introductory remarks.

Ms. Holly Phelps, Consulting Analyst, Determination of Need Program, presented Project Application No. 5-4885, Four Women Inc. to the Council. She said, "...Four Women, Inc. is proposing to establish a single specialty gynecology surgery center in Attleboro, MA. They will be providing abortion procedures, as part of a range of pregnancy-related services. For two years, Four Women, Inc. has been managing a single-specialty gynecology surgery service for a physician practice. And the intention is that when Four Women, Inc. is licensed, the physician practice will cease operations. The Center will then serve the self-pay and insured women that have been served to date by the physician practice, and most importantly, as a licensed center, they will be able to serve MassHealth women, who at this point are being referred to Boston. This involves women as far south in the state as Barnstable County, Plymouth County and Bristol County. Staff finds that with some conditions, the application meets the guidelines for freestanding ambulatory surgery centers and Determination of Need regulations. Five Ten Taxpayer Groups (TTGs) did register in connection with the project. Two in opposition and three in support. The Donald Girard Ten Taxpayer Group requested a public hearing, which was held on October 11th. With regard to the testimony at the hearing and the written comments that were submitted after the hearing, those opposed recommended a denial of the project because of moral opposition to abortion because they did not want their tax dollars to pay for these procedures and because of what they regarded as the incompleteness of the application. Those in favor of the project simply noted that abortion is a legal, medically established procedure that should be made available to poor and medically indigent women on MassHealth, the way it is available to women who have the wherewithal to pay for their own procedures. Staff continues to recommend approval of this project."

Ms. Carol Belding, President, Four Women, Inc., accompanied by Pablo Rodriguez, future medical director of the center and nationally known advocate for reproductive rights for poor women, addressed the Council. Ms. Belding said, "...What we would like to do is expand our services to serve the women of Southeastern Massachusetts. So many of whom call us on a daily basis for our services, have MassHealth, and we have to turn them away. They are distressed at the fact that they have to

travel to Boston, Worcester or Springfield. We have found next door, space to be built to specifications for clinic licensure.”

Ms. Susan Yanow, Abortion Access Group and a registered Ten Taxpayer Group, addressed the Council. She said, “...I want to voice my support and recommendation that the low-income women of Southeastern Massachusetts have the same access to services that women with funds have.”

The Ms. Marisa Howard TTG stated, “I just wanted to say thank you for your attention to this matter. Four Women is an excellent provider and there is a very clear need for Medicaid services in this area. I hope that you will approve this. I’m a very strong supporter of this.”

Mr. Donald A. Girard TTG, noted mistakes he felt were made in the process by the applicant as follows:

- No copy of the application at the Lakeville Regional Office for public viewing. Further, it was unknown to the Secretary there that the DoN office moved down the street from 10 West to 250 Washington Street, Boston. Due to this oversight, another newspaper notice announcing the application was printed and an application was placed in the Lakeville Regional Office.
- Attleboro City Hall personnel had no knowledge of the public hearing scheduled there for October 16th at 6:00 p.m..
- The application’s schematic drawing showed no operating rooms which is required under 105 CMR 140.000, and the regulations state that if an application does not meet the required criteria it cannot be amended thereafter and therefore must be denied.
- DoN regulation 105 CMR 100.533 states that a freestanding ambulatory surgery center shall document planning for community input and at a minimum any proposed ambulatory surgery shall establish an advisory board. He said that DPH staff did not respond to his request for information on this matter.
- He requested a written statement of the regulation in place for the formation and operation of an advisory board and for a statement as to the reason they were not notified when and how Four Women met the three criteria for full approval.

Ms. Holly Phelps, responded to Mr. Girard’s remarks. Ms. Phelps’s responses follow:

- Multi-specialty ambulatory surgery centers must have two operating rooms but the Department doesn’t require that for single specialty ambulatory centers. Many single specialty ambulatory centers have been approved with one operating room in the past few years by the Council.
- Formation of an Advisory Board is required by the guidelines but how the advisory board shall be formed, the number of people, and the frequency of the meetings is not spelled out. The applicant is given latitude in the guidelines to implement that requirement. One of the conditions of approval states that an advisory board must be set-up prior to licensure, this allows staff to evaluate what the applicant has arranged as an advisory board.
- There was confusion at city hall about the hearing but it was advertised in the paper and many people came.

- Many applications come into DoN and are not complete and at staff's request, the applicants give additional information.

Chairman Koh asked Ms. Phelps, "Is the applicant in compliance with the DoN guidelines?" Ms. Phelps replied, "yes."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No. 5-4885 of Four Women, Inc.**, based on staff findings, with a maximum capital expenditure of \$0 and first year incremental operating costs of \$476,678 (September 2000 dollars), that a copy of the staff summary be attached and made a part of this record as **Exhibit Number 14,690**. As approved, this application provides for the development of a single-specialty freestanding ambulatory gynecology surgery center with one (1) operating room located in a medical/dental office building at 152 Emory Street in Attleboro. This Determination is subject to the following conditions:

1. Prior to licensure, the applicant shall establish an advisory board in accordance with the Guidelines.
2. Prior to licensure, the applicant shall submit to the Department a schedule of charges per procedure for all payers.
3. The applicant shall meet the requirements for structure and design found in the Department of Public Health Clinic Licensure Regulations (105 CMR 140.000).

Staff's recommendation was based on the following findings:

1. The applicant is proposing to establish a single-specialty freestanding ambulatory gynecology surgery service with one operating room located in a medical office building at 152 Emory Street, Attleboro, MA.
2. The health planning process for this project was satisfactory.
3. The applicant has demonstrated need based for the proposed project, as discussed under the health care requirements factor of the staff summary.
4. The project meets the operational objectives factor of the Guidelines.
5. The project, with adherence to a certain condition, meets the standards compliance factor of the Guidelines.
6. There is no maximum capital expenditure for this project.

7. The recommended incremental operating costs are reasonable based on similar, previously approved projects.
8. The project is financially feasible and within the financial capability of the applicant.
9. The project meets the relative merit requirements of the Guidelines.
10. The community health service initiatives are waived for this project.
11. Katrina Anderson, 102 Wallace Street, Somerville, MA 02144; Donald A. Girard, 47 Towne Street, North Attleboro, MA 02760; Marissa Howard, 58 Glen Road, Jamaica Plain, MA 02130; Margaret E. Whitbread, 65 Blake Road, Wrentham, MA 02093; and Susan Yanow, 221 Norfolk Street, Cambridge, MA 02139 registered in connection with this project.

REGULATIONS:

REQUEST FOR EMERGENCY PROMULGATION OF AMENDMENTS TO HOSPITAL LICENSURE REGULATIONS 105 CMR 130.000 ET SEQ. REGARDING THE DISCONTINUANCE OF ESSENTIAL SERVICES:

Dr. Paul Dreyer, Director, Division of Health Care Quality, presented the request for emergency promulgation of proposed amendments to the hospital licensure regulations 105 CMR 130.000. He said in part, "...The proposed amendments govern the discontinuance of essential health services and implement section 2 of Chapter 141 of the Acts of 2000 – the new managed care reform law. Section 2 requires that the Department define essential services, and sets out a process that hospitals must follow if they choose to discontinue an essential service. Emergency promulgation is necessary due to the emergency preamble, which became effective upon the signature of the Governor on July 21, 2000, and it is important that implementing regulations be in place prior to any proposed discontinuance of hospital services."

Dr. Dreyer continued, "Under the law, hospitals must provide 90 days advanced notice of closure to the Department, which, in turn, must hold a public hearing on the proposed closure of an essential service, if the Department determines that the service the hospital is proposing to close is essential. As a result of that public hearing, the Department has to make a determination as to whether the proposed closure will significantly reduce access to necessary services and affect the health status and availability of the services to people in the service area. That's what is in the statute. What we have proposed in these emergency regulations is that essential services are those services that we set out in hospital licensure regulations as specifically licensed services. They include most of the inpatient services that people think of when they think about a hospital. That is Medical/Surgical Services, Intensive Care Unit services, Coronary Care Unit services, Burn Unit, Pediatric Service, Pediatric Intensive Care, Maternal-Newborn Service, Special Care Nursery Service, Continuing Care Nursery Service, Psychiatric Service, Substance Abuse Service, Chronic Dialysis Service, Chronic Care Service, Rehabilitation

Service, Skilled Nursing Facility Service, Intermediate Care Facility Service, Ambulatory Care Services, Emergency Services, Birth Center Services, Hospice Service, Cardiac Catheterization Services, Hematopoietic Progenitor/Stem Cell Collection, Processing and Transplantation Services. Services that we excluded are Hematopoietic Stem Cell Transplantation, which is available at only some tertiary facilities and SNF and ICF, which are nursing home services with a separate license. We have included the definition of a campus as a site on the license of a hospital that provides an essential service so that if a campus is closed that would trigger the public hearing process.”

The regulations specify under 105 CMR 130.122 the following:

- (D) In the event that the Department finds that a hospital proposes to discontinue an essential health service at a campus, or discontinue services entirely at a campus, the Department shall publish a notice of a public hearing in the legal notice section of local newspapers serving residents of the hospital’s service area at least 21 days prior to the date of the hearing. The notice shall set forth the name and address of the hospital, briefly describe the proposed modifications in existing services, and indicate the date, time and location of the hearing. The hearing shall take place in the hospital’s service area no later than forty-five (45) days prior to the proposed discontinuance date set out in the hospital’s notice submitted pursuant to 105 CMR 130.122(C). At the public hearing, the hospital shall describe the services to be closed, plans for alternate access to the service, and shall afford the opportunity for interested parties to present their comments on the hospital’s proposal.
- (E) The Department shall make a determination as to whether the discontinued service is necessary for preserving access and health status in the hospital’s service area. In making its determination, the Department shall consider the evidence presented at the public hearing, the current utilization of the service, the capacity of alternative delivery sites to provide the service, travel times to alternative service delivery sites, the clinical importance of local access to the service, and any other relevant information available to the Department.
- (F) If the Department finds that the discontinued service is necessary for preserving access and health status in the hospital’s service area, the hospital shall, within 15 business days of such finding, submit a plan for assuring access to such necessary service(s) following the hospital’s closure of the service(s). The plan must include the following elements:
 - (1) Information on utilization of the service prior to proposed closure
 - (2) Information on the location and service capacity of alternative delivery sites
 - (3) Travel times to alternative service delivery sites
 - (4) An assessment of transportation needs post discontinuance and a plan for meeting those needs

- (5) A protocol that details mechanisms to maintain continuity of care for current patients for the discontinued service
- (6) A protocol that describes how patients in the hospital's service area will access the services at alternative delivery sites.

After consideration, upon motion made and duly seconded, it was voted (unanimously): that the **Request for Emergency Promulgation of Amendments to the Hospital Licensure Regulations 105 CMR 130.000 et. seq. Regarding the Discontinuance of Essential Services be approved and promulgated; that a copy be forwarded to the Secretary of the Commonwealth; and that a copy of the emergency regulations be attached and made a part of this record as Exhibit No. 14,691.** These emergency regulations will be in effect for 90 days, and must return to the Council for final promulgation.

REQUEST FOR EMERGENCY PROMULGATION OF REGULATIONS – 105 CMR 128.000 HEALTH INSURANCE CONSUMER PROTECTION REGULATIONS (IMPLEMENTING M.G.L.c.1760, AS REQUIRED BY CHAPTER 141 OF THE ACTS OF 2000, “AN ACT RELATIVE TO MANAGED CARE PRACTICES IN THE INSURANCE INDUSTRY”):

Attorney Carl Rosenfield, Deputy General Counsel, Department of Public Health, presented the emergency regulations to the Council (105 CMR 128.000) for approval. Attorney Rosenfield noted, “By the way of background, Chapter 141 of the Acts of 2000 established within the Department an Office of Patient Protection, and also created a more comprehensive system of regulation of managed care organizations through the creation of a new Chapter 1760, which the Office of Patient Protection is responsible for administering. In 1760, the Department has been given responsibility for four discrete sections, and they really break down as: Section 13, which governs the managed care organizations’ internal grievance procedures; Section 14, which sets up a requirement for an independent external review; Section 15, which we often refer to as the continuity of care provision, but really involves certain provider disenrollments from plans and continuity of care subsequent to those disenrollments, certain rights to self-referral for certain services, and finally, even a couple of mandated service coverage provisions - it’s sort of a catchall section; and Section 16, which deals with sort of practitioner rights to make clinical decisions, but also the corresponding right of managed care organization carriers to establish guidelines for determining medical necessity. Those provisions of Chapter 1760 become effective January 1, 2001...” Attorney Rosenfield said that the Department had a volunteer mediation group contact the managed care organization groups to find out what they were presently doing in regard to internal grievance procedures and external reviews that they may have set-up pursuant to accreditation standards that predated this statute.

Attorney Rosenfield continued, “The regulations break out into basically four areas. In two of the areas, those implementing Sections 15 and 16, we have merely carried forward in the emergency regulations the statutory language. We haven’t attempted any further clarification since the language in these sections is fairly detailed. We end up doing that as a result of input we receive in the public hearing and

public comment process. We felt it was more important to concentrate on the internal grievance and the external review process. We have done a couple of things. The statute really requires the internal grievance procedure to be completed in thirty days, and that's a much different time frame than many of the carriers currently operate under. They can go up to ninety days. They have processes that involve the opportunities for members to come in, meet with the review committee. They could have two, maybe three levels of internal review. The statute doesn't allow for that and it defines grievance in very broad terms - in terms so broad that it could be construed to include any inquiry an individual subscriber might have of a plan. What we have done in these regulations is to reflect that there is a class of content that really isn't a grievance. It is more an inquiry. It is a matter that can be readily resolved to the member's satisfaction in a relatively short period of time. For example, your name spelled wrong on your membership card. You call member services, they say you are right and update and send you a new card. There is no need for that transaction to trigger the formal written notifications and the other details of the internal grievance procedure. The same goes for a billing error. If they don't resolve it, you still have the opportunity to plug into the formal grievance procedure. Things that are always in the grievance procedure are adverse determinations, and that's a denial of service that was otherwise covered, based on the determination that the service wasn't medically necessary. Those reviews are always in the internal grievance procedure. Correspondingly, the external process, which we are responsible for setting-up, deals only with decisions that are adverse determinations. One can have a whole range of complaints that aren't eligible for the external review. We have tried to clarify the statutory language in the regulations, and have provided for the Office of Patient Protection to screen the requests for external review after the internal process has been exhausted, to make sure that we are only sending off to the external review entities those matters that involve adverse determinations. We have issued an RFR to obtain the services of three external review agencies, which is the statutory requirement. Unfortunately, we have only received two responses but both appear to be well qualified and have experience doing these reviews in other states. We will probably reissue the RFR in an attempt to get an additional agency so that we meet the statutory requirement of three."

It was noted that there will be five public hearings in various locations in the state, all in the first week in February and in coordination with the Division of Insurance, that is have the hearings on the same day and location but different times.

Council Member Askinazi said in part, "... that since the passage of the catastrophic 1997 Budget Act we have seen the deconstruction of the American health care system. In Massachusetts, we have gone from 120 hospitals to about 80 in fifteen years; two-thirds of the hospitals are in the red. The teaching of new doctors in pediatrics has fallen to an incredible low level because there is no reimbursement. Pediatrics is a crucial area for clinical teaching because one and two-year-old kids don't speak to you very much...In that context, in an emergency, is why I think emergency regulations are so appropriate."

Dr. Askinazi noted further that in 128.100, it should include adult mental health services along with the children already included; and in 128.411 it would be helpful that if a person serves on a grievance committee that individual should be prohibited for a period of at least three years from serving as any kind of independent consultant for profit representing anyone who's coming before a grievance committee, whether it is the caregiver or the provider; in regards to 128.301, he suggested that these

things should be advertised in print and radio so that everybody is informed; and lastly, that if the provider organization is not complying with the regulations in full, they should come before the Commissioner of Public Health or the Public Health Council. Attorney Rosenfield responded to these suggestions by Dr. Askinazi stating that the Department was restricted by the language in the statute in regards to these above suggestions and that enforcement will be handled by the Division of Insurance.

After consideration, upon motion made and duly seconded, it was voted unanimously [Council Member Sherman did not vote] to approve the **Request for Emergency Promulgation of Regulations – 105 CMR 128.000 Health Insurance Consumer Protection Regulations (Implementing M.G.L.c.1760, as required by Chapter 141 of the Acts of 2000, “An Act Relative to Managed Care Practices in the Insurance Industry”)**; that a copy of the emergency regulations be forwarded to the Secretary of the Commonwealth for promulgation; and that a copy be attached and made a part of this record as **Exhibit No. 14,692**.

DETERMINATION OF NEED PROGRAM:

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED DoN PROJECT NO. 4-3951 OF CARITAS SOUTHWOOD HOSPITAL AND PROJECT NO. 4-3952 OF CARITAS NORWOOD HOSPITAL – PROGRESS REPORT ON COMPLIANCE WITH CONDITIONS OF APPROVAL OF TRANSFER OF OWNERSHIP:

Ms. Joyce James, Director, Determination of Need Program, presented the progress report on DoN Projects No. 4-3951 and 4-3952 to the Council. She said, “I’m here today to report on the progress of Caritas Norwood Hospital’s compliance with three conditions relating to the transfer of ownership approval of the former Norwood and Southwood Hospitals to Caritas Christi Corporation. Based on the report submitted by the Hospital and by the Neponset Valley Community Health Coalition, we find that the Hospital is in substantial compliance with the three conditions relating to mental health services, staffing and landfill. We also find that additional time is needed for the hospital to reach full compliance. We are recommending that one year from now the hospital submit a report on its progress in (a) establishing and implementing a dedicated mental health services exit plan; (b) increasing the number of regular full-time and half-time staff nurses; and (c) completing the landfill of the Southwood Hospital site. We would also like to commend both the hospital and the Coalition on their collaborative efforts in achieving the objectives of these conditions.” The applicant did not address the Council.

Attorney Laurie Martinelli, Health Law Advocates, representing the Neponset Valley Community Health Coalition, stated, “We are here to support the staff report and to really commend Caritas for a very collaborative working relationship with the Coalition. You would be very pleased if you saw the level of cooperation that’s going on. We are in support to bring the three issues back, and the big challenge for us substantively, like a lot of communities, is the mental health issue. I know it is something Caritas is committed to and something that the Coalition is very committed to work towards.”

After consideration, upon motion made and duly seconded, it was voted (unanimously) to approve the recommendation by staff to have **Caritas Norwood Hospital** submit in one year a report on its progress in compliance with conditions of approval relating to the establishment of plans for dedicated mental health exit services, staffing, and landfill of previously approved **DoN Projects No. 4-3951 and 4-3952**.

The meeting adjourned at 11:10 a.m.

Howard K. Koh, M.D., M.P.H.
Chairman

LMH/lmh